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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,897	02/20/2004	John T. Santini JR.	17648-0027	7164

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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02/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/783,897	Applicant(s) SANTINI ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/12/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

Amendment and terminal disclaimers filed on 12/12/07 has been entered.

Claims 55-103 are present for examination.

Applicant's arguments filed on 12/12/07 have been fully considered but are not persuasive.

Therefore, claims 55-103 are rejected in the same ground rejections as set forth in the office action mailed 8/24/07. Please see Response to Arguments below.

The IDS have been considered in view of the amendments filed on 12/12/07.

The claim 77 rejections under 35 USC §112, 2nd paragraph have been withdrawn in view of amendments filed on 12/12/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not disclose how/what make two reservoirs formed a single reservoir. According to Fig. 9c, it shows that there is only one/single reservoir. However, applicant denotes two reservoirs with two portions in one/single reservoir. (Please see Response to Argument below).

For examining purpose, Examiner is considering that any single reservoir can be read on claim 58.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al. (US 5,366,454).

Regarding claims 77, 91 and 97-98, Currie discloses, Fig. 1-8, a medical device comprising: a substrate 12 or 22; a reservoir 16, it is noted that there is only one reservoir shown in Figs. 1-6 and 8, however, there are plurality of compartment (reservoir) in the medical device (see abstract); reservoir provided in spaced positions across at least one surface of the substrate; reservoir caps (24 or 62; 64, 66, 68) covering the reservoir; and control circuitry for selectively disintegrating the reservoir caps to open the reservoirs (see abstract). Currie uses rupture method for reservoir caps to open the reservoirs for fluids entering into the compartment/reservoir; and upon application of an electric potential generated by the control circuitry (Fig. 6).

Regarding claims 78-80, the molecules comprise molecules useful in medical diagnostics.

Regarding claims 81-83, 92-93, the substrate comprises silicon; two or more layers bonded together.

Regarding claims 84, 86-88 and 95-96, comprising a biosensor; power source. Regarding claims 85 and 94, the reservoir cap comprises a metal film (62-68). Regarding claims 89 and 102, the device adapted for implantation into a patient. Regarding claim 98, the control circuitry comprises a cathode and a power source, wherein at least one reservoir cap 24 or 24' is an anode, and wherein application of an electric potential between the cathode and anode causes at least one of the reservoir caps to disintegrate.

Regarding claims 90 and 99-101, the reservoir comprises drug molecules.

Regarding claim 103, it is noted that the product-by-process limitation "the reservoirs are fabricated using micro-fabrication techniques" has not been given weight in determining the patentability of the device claim. See MEPE §2113.

Claim Rejections. 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-76, 85 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al. (US 5,366,454). (Please also see Response to Arguments # 5-6 for more details).

Currie discloses, Figs. 8, an implantable device comprising: a substrate 12, 22; at least two reservoirs 16 in the substrate. It shows only one reservoir, however, it is noted that there are plurality of reservoir in the medical device (see abstract or col. 5, lines 37-40); the release system disposed in the reservoir, the release system comprising drug molecules for release; a reservoir cap 24 positioned over the reservoir; wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir, cap is actively controlled. The membrane to be ruptured and allowing body fluids to enter into the compartment (reservoir) for mixing with the medicine contained therein so that the medicine is released in admixture with the body fluids through the delivery opening into the body fluids through the delivery opening into the human body (see abstract, lines 17-27).

Currie discloses the reservoir cap (membrane 24 or 24') formed of silicon material. The silicon membrane 24 is anodically bonded to the silicon body 12 (col. 5, lines 37-58). In other words, silicon membrane can be used as anode material. Currie does not disclose the reservoir cap formed of metal. Applicant discloses his metal reservoir cap is formed of conductive material and serves as an anode (page 21, lines 24-25 or page 33, lines 30-31). Therefore, it would have been obvious to one ordinary skill in the art substitute of one known material (such as silicon for metal) for another, since it would have yielded predictable result to one ordinary skill in the art at the time of the invention.

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Additionally, Auburn (US 3,894,457) and Sapru et al. (US 4,623,597) are evidence showed that silicon (Si) and metal can be served as anode material in electrochemical.

Auborn discloses that lithium metal (col. 3, lines 25-27) or silicon (col. 3, line 46) is anode material. Sapru discloses that anode material include Zn, Nb, La, Si, Sc and Y (col. 12, line 21-22) or Cu, Mn, C, Fe, Ni, Al, Co, Mo, W, Li and Re (these are metal elements) (col. 12, lines 28-29).

Regarding claim 56, the substrate is comprised of two or more substrate (12 and 22) portion bonded together.

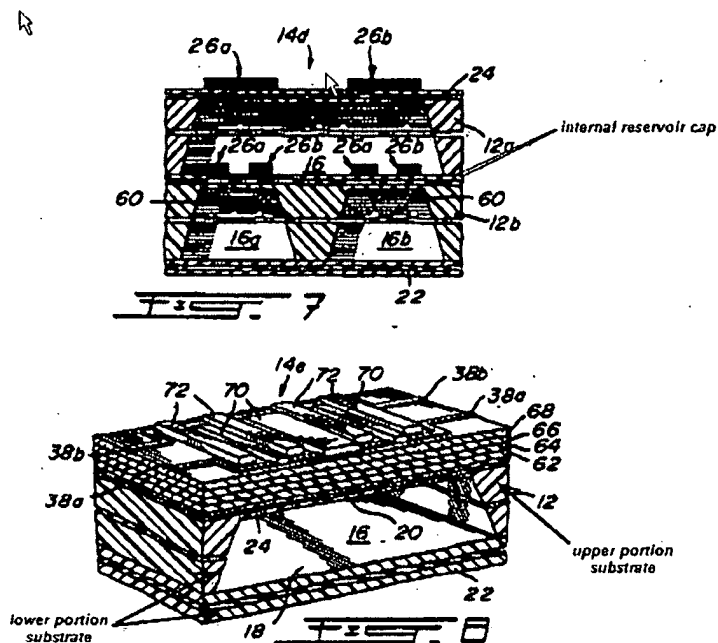
Regarding claim 57, the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap (see Fig. 8 below).

Regarding claim 58, as best as understood, wherein a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion and the two reservoir sections forming a single reservoir (see Fig. 8 below).

Regarding claim 59, the reservoir section in the lower substrate has a volume that is greater than the volume of the reservoir section in the upper substrate portion.

Regarding claims 57 and 61-62, as best as understood, (Fig. 7 below), the substrate comprises an upper substrate portion 12a adjacent the reservoir cap and a lower substrate portion 12b distal the reservoir cap; wherein the lower substrate portion is provided with an internal reservoir cap interposed between a reservoir section of the upper substrate portion and a reservoir section of the lower substrate portion, wherein release of the molecules from the reservoir section in the lower substrate portion is controlled by diffusion through or disintegration of the internal reservoir cap.

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Regarding claims 63-64, the disintegration of the reservoir cap is activated by application of electrical energy through the reservoir cap (see abstract, and Fig. 6).

Regarding claims 65-67, Currie discloses the claimed invention except for the release system comprises matrix material or biodegradable or bioerodible polymeric material; and the drug molecules comprises anesthetics, vaccines, chemotherapeutic, etcIt would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials mentioned above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 68, the disintegration of the reservoir caps is controlled by a preprogrammed microprocessor.

Regarding claims 69-76, similar to rejection of claims 55-68 above. Furthermore, Currie discloses that the device is activated by disintegration of the reservoir cap by direct application of an electrical potential through the reservoir cap (see abstract, or col. 2, lines 47-65).

Response to Arguments

Applicant's arguments filed 12/12/07 have been fully considered but they are not persuasive.

I) Response to the Rejection under §112:

Examiner agrees with the explanation of Applicant that "there are an upper reservoir section (720a) and a lower reservoir section (720b), and these are in communication with one another" (page 12 of Remarks filed on 12/12/07). However, Figs. 9c-9d or in the specification on page 33, line 16-page 34, line 3 do not disclose the limitation that "the two reservoir sections formed a single reservoir" as in claims 58 and 61.

II) Response to the Rejection on Prior Art:

1) Applicant argues that nowhere is it disclosed that closure member 22 ruptures or otherwise opens; it remains seal.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., closure member ruptures or otherwise opens; it remains sealed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2) Applicant argues that disintegrating the reservoir caps is not the same as rupturing them (page 13, last paragraph of Remarks).

In response, the definition of disintegration means that the condition of being decayed; breakdown, decomposition (see www.answers.com). Similarly, rupture means that the process or instance of breaking open or bursting, or the state of being broken open.

Therefore, the drug molecules is released from the device of Currie by disintegration/ruptures of the reservoir cap.

3) In claims 84, Applicant argues that Currie fails to disclose or suggest a biosensor.

In response, Currie discloses that "a detector means (same as biosensor of device of Applicant)...the electrical signal supplying means can also incorporate means for receiving an externally transmitted command signal for initiating operation of the switching circuit, as well as multi-sensor means

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for activating the switching circuit upon detection of specific chemical or biological conditions, such as arterial pressure, pH, glucose concentration, insulin concentration, etc... (col. 4, lines 32-64).

4) Applicant argues that the reservoir caps comprise a metal film, are not anticipated for the additional reason that Currie discloses only a silicon membrane. Currie does not disclose the reservoir cap formed of metal.

In response, because of the Applicant claims very broadly, therefore Examiner interprets very broadly that the reservoir cap (electrically conductive thin film 66) is covering the reservoir 16, and the element 66 can be a reservoir cap made of metal film.

5) In rejection of claims 55-76, 85 and 94, Applicant argues that "in the sense of the term of art in Currie, "anodically bonding" does not mean to use silicon as an anode";

Applicant further states that "Currie does disclose that the silicon reservoir membrane 24 is anodically bonded to the silicon body 12, but it appears that Examiner does not understand what the term of art mean.

In response, Examiner would like to use additional reference such that Miyazaki (US 6,537,938) is evidence to against what Applicant states above. Miyazaki discloses that anodic bonding is a method wherein a glass is heated to a temperature at which readily mobile cations contained in the glass are readily mobile, and using the silicon as an anode and the glass as a cathode (col. 1, lines 28-33).

Currie discloses that silicon membrane 24' (as a cap of reservoir 16) is anodically bonded to the silicon body 12' (col. 5, lines 57-58). Based on what Miyazaki explains about anodic bonding method, one skill in the art would recognize that Currie uses silicon membrane 24 as an anode.

Furthermore, Applicant also states that similar to what Examiner explained above that the electrons from the Si are drawn to the anode (Remarks filed on 12/12/07 on page 16, line 9).

6) Applicant argues that: Auburn (US 3,894,457) nor Sapru (US 4,623,597) suggest of silicon being an anode.

In response, Auburn discloses that lithium metal (col. 3, lines 25-27) or silicon (col. 3, line 46) is anode material. Sapru discloses that anode material include Zn, Nb, La, Si, Sc and Y (col. 12, line 21-22) or Cu, Mn, C, Fe, Ni, Al, Co, Mo, W, Li and Re (these are metal elements) (col. 12, lines 28-29).

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Upon reading the references, thus, it would have been obvious to a person of ordinary skill in the art to try the metal for anode (as discussed in Auburn or Sapru) in attempt to substitute for silicon, but metal or silicon can do same function as anode, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Quynh-Nhu H. Vu
Examiner
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